PCT/EP04/010347

Int'l Filing Date

:

September 15, 2004

## AMENDMENTS TO THE SPECIFICATION

Please delete the header DESCRIPTION immediately after the Title of the Invention.

Please add the following paragraph immediately after the Title of the Invention:

Cross-Reference to Related Applications

This Application is a US National Phase of the International Application No. PCT/EP04/010347 filed September 15, 2004 designating the US and published in German on April 14, 2005 as WO 05/032391, which claims priority of German Patent Application No. 103 43 826.2, filed September 22, 2003.

Please add the following headers immediately before line 5 on page 1 of the English translation of the Specification:

BACKGROUND OF THE INVENTION

Field of the Invention

Please add the following header immediately after line 6 on page 1 of the English translation of the Specification:

Description of the Related Art

Please add the following header immediately after line 15 on page 2 of the English translation of the Specification:

SUMMARY OF THE INVENTION

Please revise the paragraph on lines 17-20 on page 2 of the English translation of the Specification as follows:

The invention is therefore based on the problem of providing a smaller, lighter locator of the kind mentioned in the preamble that can be attached to the bone in a minimally invasive way. A further objective is to provide a medical navigation system matched to such improved locators.

Please replace the paragraph on lines 22-23 on page 2 of the English translation of the Specification with the following three paragraphs:

In accordance with one embodiment, a bone-fixed locator for use with a navigation system to determine the spatial position and location of a body part of a mammal is provided. The navigation system determines the spatial position and location of the body part based on signals

PCT/EP04/010347

**Int'l Filing Date** 

:

**September 15, 2004** 

from the locator. The navigation system has a recording device connected to a control an evaluation device thereof. The bone-fixed locator comprises a body with fewer than three target markers, the target markers configured to communicate a signal to a recording device of a navigation system. The bone-fixed locator also comprises an engagement portion attached to the body, the engagement portion configured for engagement in a bone of a mammal.

In accordance with another embodiment, a navigation system for determining the spatial position and location of a body part of a mammal is provided. The navigation system comprises a recording device and a control and evaluation device connected to the recording device. The navigation system also comprises at least two locators rigidly fastened to a bone, the locators operably connected to one another via the bone, each locator comprising a body and fewer than three target markers mounted thereon. The recording device is configured to receive signals from the target markers, and the control and evaluation device is configured to evaluate said signals to establish a bone-fixed co-ordinate system.

In accordance with yet another embodiment, a method for determining the spatial position and location of body parts of a mammal is provided. The method comprises fastening at least two locators to a bone, the locators operably connected to one another via the bone. Each locator defines a pivot axis that extends between fewer than three target markers on the locator and an engagement portion of the locator, the locator being pivotable about the pivot axis. The method also comprises recording signals communicated by each target marker and evaluating said signals to determine the spatial position and location of a body part.

Please add the following header and paragraph immediately after line 2 on page 4 of the English translation of the Specification:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of an optical navigation system including a bone-fixed locator, in accordance with one embodiment.

Please add the following header immediately before line 4 on page 4 of the English translation of the Specification:

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

PCT/EP04/010347

Int'l Filing Date

:

**September 15, 2004** 

Please revise the paragraph on lines 12-19 on page 4 of the English translation of the Specification as follows:

In a further preferred configuration, the engagement portion is in the form of a self-tapping thread – which is more preferably also self-drilling. Using such a screw, the locator according to the invention—can be reliably fixed to the bone or bone portion the position of which is to be determined using a small number of simple manipulations and with little invasiveness. Positional displacements in the longitudinal direction are virtually ruled out, as is unintentional loosening. In a locator configuration having two target markers, the thread axis lies preferably in the (above-mentioned) line connecting them.

Please revise the paragraph on lines 5-16 on page 5 of the English translation of the Specification as follows:

For that purpose, especially, there is implemented in the control and evaluation device (11) an evaluation program for the associated evaluation of signals provided by target markers (3c, 3d, 5c, 5d) on the two or more locators (3, 5) so that the signals of at most two target markers on one and the same locator are entered in the position determination. Even when, therefore, locators having three or more target markers are to be used in a navigation system—of the kind according to the invention, that configuration of the control and evaluation device ensures that the position determination is carried out on the basis of the data of a plurality of locators rigidly connected by way of the bone and not on the basis of the signals of an individual locator. In that respect, locators having, for example, three or more target markers of which, however, only two are used in the sense of the invention—would also be regarded as locators lying within the scope of the invention.

Please revise the paragraph on lines 18-20 on page 5 of the English translation of the Specification as follows:

Advantages and useful features of the invention will otherwise be found-in the dependent claims as well as in the following description of a preferred embodiment with reference to the single Figure 1.

Please revise the paragraph on lines 22-30 on page 5 of the English translation of the Specification as follows:

Int'l Appl. No. : PCT/EP04/010347 Int'l Filing Date : September 15, 2004

The Figure 1 shows a simplified diagrammatic view of an optical navigation system 1 for medical use, the important components of which are two bone-fixed locators 3 and 5 of the kind according to the invention, IR illumination sources 7A and 7B, a stereo-camera arrangement 9 having two IR cameras 9a and 9b and an evaluation unit 11 connected thereto. In respect of the illumination unit 7 and the stereo-camera arrangement 9, the system has no special features in comparison with known navigation systems. In the evaluation unit 11, however, a special evaluation program is implemented which allows combined evaluation of the light signals coming from the two locators 3 and 5 to create a set of position data.

## Please revise the paragraph on page 5, line 32 – page 6, line 3 of the English translation of the Specification as follows:

In the illustrated embodiment, the The-locators 3 and 5 are identically constructed, each having an L-shaped body 3a and 5a, a self-cutting thread 3b and 5b mounted thereon and two retroreflecting spheres 3c, 3d and 5c, 5d, respectively, on the elongate portion of the body. In the illustrated embodiment, the locators 3, 5 They are screwed into a tibia T of a patient, spaced apart from one another, and define the reference of the tibia T. Screwing-in is effected without any appreciable prior exposure of the fixing region and is largely free of soft-tissue irritation and impairment of the ligaments in the knee joint or foot joint region.

## Please add the following paragraph immediately after line 10 on page 6 of the English translation of the Specification:

Of course, the foregoing description is that of certain features, aspects and advantages of the present invention, to which various changes and modifications can be made without departing from the spirit and scope of the present invention. Moreover, the locator or optical navigation system need not feature all of the objects, advantages, features, and aspects discussed above. Thus, for example, those skilled in the art will recognize that the invention can be embodied or carried out in a manner that achieves or optimizes one advantage or a group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein. In addition, while a number variations of the invention have been shown and described in detail, other modifications and methods of use, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is contemplated that various combinations or sub-combinations of these specific features and

PCT/EP04/010347

Int'l Filing Date

September 15, 2004

aspects of embodiments may be made and still fall within the scope of the invention. According,

it should be understood that various features and aspects of the disclosed embodiments can be

combined with or substituted for one another in order to form varying modes of the discussed

locator and optical navigation system.

:

Please replace the header on page 7 of the English translation of the Specification

with the following headers:

**BONE-FIXED LOCATOR AND OPTICAL NAVIGATION SYSTEM** 

ABSTRACT OF THE DISCLOSURE

Please revise the paragraph on lines 3-10 on page 7 of the English translation of the

Specification as follows:

A bBone-fixed locator (3, 5) for use with as reference of a navigation system (1) for determining

the spatial position and location of a body part[[s]] of a mammal includes a body with fewer than

three target markers and an engagement portion attached to the body. The engagement portion is

configured for engagement with a bone of a mammal. The target markers communicate signals

to a recording device of the navigation system that, having a recording device, especially a

stereo-camera arrangement (9), for locat[[ing]]es the position of locators on the basis of said

signals. provided by target markers on the locators and The navigation system also includes

having-a control and evaluation device (11)-connected to the recording device and configured to

evaluate said signals, there being fewer than three target markers (3c, 3d, 5c, 5d) provided on a

body (3a, 5a) for giving a signal to the recording device and an engagement portion (3b, 5b)

configured for engagement in a bone of the mammal.

Please delete the following line immediately after line 10 on page 7 of the English

translation of the Specification:

(Figure)

Please replace the first two headers on page 8 of the English translation of the

Specification with the following header:

**WHAT IS CLAIMED IS:** 

-6-